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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,194	02/02/2004	Douglas Hovey	029318-1001	3657

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EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
07/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,194	HOVEY ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 and 19-99 are pending in this application.

Action Summary

1. The rejection of claims 1, 2, 4, 5, 10, 12, 39-41, 44, 48, 53, 54 and 70 under 35 U.S.C. 102(e) as being anticipated by Wertz et al. is herby withdrawn in view of the signed Declaration under 37 CFR 1.132 filed March 20, 2007.

2. The rejection of claims 17 and 19-35 under 35 U.S.C. 103(a) over Karlsson et al. is hereby withdrawn in view of applicants arguments that Karlsson et al. do not teach sterilizing the fluticasone particles by a sterile filtration method.

3. The rejection of claims 1-11, 16, 39-54, 59-76 and 81 under 35 U.S.C. 103(a) over Karlsson et al. is being maintained for the reasons stated in the office action dated January 29, 2007.

4. The rejection of claims 82-99 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is hereby withdrawn in view of applicant arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-11, 16, 17, 19-35, 39-54, 59-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (US 2002/0065256 A1).

Applicants claim a fluticasone composition comprising particles of fluticasone having a particles size of less than 900 nm and at least one surface stabilizer.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Karlsson et al. disclose a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory conditions of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate).

¶ [0017] teach the particle size as less than 10 microns. ¶ [0031] teach the use of the composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶ [0035] teach suitable surfactants that can be employed in the composition, mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particle size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Karlsson et al. do not teach specific examples using fluticasone as claimed by applicant.

Finding of prima facie obviousness

***Rational and Motivation* (MPEP §2142-2143)**

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cited glucocorticosteroids in the instant invention. As paragraph [0016] teaches examples of glucocorticosteroids one of ordinary skill could substitute any one of the glucocorticosteroids listed (i.e. fluticasone) to achieve the same desired results of

treating allergic and/or inflammatory condition of the nose or lungs (e.g. chronic obstructive pulmonary disease, asthma, etc.).

Response to Arguments

6. Applicant's arguments filed March 20, 2007 have been fully considered but they are not persuasive.

Applicants argue that Karlsson does not provide motivation to make a composition having a drug particles size in which 50% of the particles are less than 1 micron, as Karlsson is directed to particles having much larger sizes. The examiner disagrees. As stated in the previous office action the particles of Karlsson can have a mass median diameter of less than 1 micron [0017] and the claimed invention claim particle size of less than 900 nm, which fall into the range of less than 1 micron and is thus obvious. Applicant argues that the 1 micron particle of Karlsson falls within the bottom range of the particle size range. Although the particle size of Karlsson is in the bottom range, the size range still overlaps. Therefore, the range reads on the claimed composition range and the characteristics of the composition would be the same. Applicant merely claims a composition of particles having a particular particle size and a surface stabilizer. Therefore, any composition having the particle size and stabilizer reads on the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-17 and 19-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims that the particles size of the fluticasone is "less than about" 900 nm. It is unclear to the examiner what is meant by "less than about". The claims should read that the particles are "less than" 900 nm or "about" 900 nm.

Claim Objections

8. Claims 13, 35, 56 and 78 contain the trademark/trade name POLYQUAT™, MIRAPOL™ and ALKAQUAT™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Conclusion

9. Claims 1-17 and 19-99 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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